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10/554,094	10/21/2005	Katsuyoshi Nagao	06854.0046	6586

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,094	NAGAO ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,11-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7, 11-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. PCT/JP/2004/005547, filed on 19 April 2004 has been received.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US Patent 4,502,616) in view of Takanashi et al. (US Patent 4,537,305) in view of Itoh et al. (US Patent 6,042,906).

5. Regarding claim 1, Meierhoefer discloses an ampoule comprising:

a flexible container body (column 3, lines 56-65 and Fig. 3, vials or ampoules 12);

a fusion-bonded portion which seals a mouth of the container body (column 4, lines 25-36 and Fig. 3, seal 44); and

a holder tab connected to the fusion-bonded portion for wrenching off the fusion-bonded portion (column 4, lines 25-36 and Fig. 3, key 26).

The ampoule of Meierhoefer comprises plastic (column 3, lines 56-65), therefore it naturally follows that it is capable of preventing drug permeation.

Meierhoefer discloses the invention substantially as claimed. See above. However, Meierhoefer lacks a container body including three or more layers as claimed [claim 1]. Takanashi discloses a medical storage container (column 1, lines 9-14) having:

an innermost layer composed of a polyolefin (column 3, lines 4-14 and Fig. 2, inner layer 3 comprising polyolefin); and

an outmost layer composed of a polyolefin (column 3, lines 4-14 and Fig. 2, outer layer 1 comprising polyolefin). Takanashi provides the advantage of a thermally resistant polymer (column 3, lines 27-31). This advantage is important, since medical containers are routinely sterilized using high temperatures. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer as discussed with the polyolefin of Takanashi in order to provide thermally resistant polymer during a sterilization process.

Meierhoefer in view of Takanashi discloses the invention as substantially claimed, see above. However, Meierhoefer in view of Takanashi lacks a polycycloolefin

as claimed [claim 1]. Itoh discloses an impermeable container (column 1, lines 6-13) having an intermediate layer comprising a polycycloolefin layer (column 6, lines 40-47 and Fig. 3, intermediate layer 12 comprising cyclic olefin copolymer). Itoh provides the advantage of retaining flavors, therefore it naturally follows that a polycycloolefin is resistant to movement of volatile substances that may be contained within a medical container. In other words, the ability to retain flavors as disclosed by Itoh translates into an ability to resist movement of volatile substances. This is a valuable advantage, since medications may comprise volatile substances, which require preservation in order to retain their potency. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the polycycloolefin of Itoh in order to provide low moisture permeability as taught by Itoh, and additionally resist movement of volatile substances.

Regarding the limitation of a "…container body [that] is molded by holding [a] parison," Examiner notes that claims 1 and 3-12 are drawn to a device, not a method of manufacture.

6. Regarding claim 3, Meierhoefer discloses the invention as substantially claimed, see above. However, Meierhoefer lacks an additive as claimed [claim 3]. Takanashi discloses a layer provided as other than an innermost layer and composed of a material containing an oxygen absorbing agent (column 4, lines 51-55 and Fig. 2, deoxidizer 13). Takanashi provides the advantage of absorbing oxygen, to prevent degradation of a medical solution (column 1, lines 39-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of

Meierhoefer in view of Komatsu as discussed with the oxygen absorbing agent of Takanashi in order to prevent degradation of a medical solution as taught by Takanashi.

7. Regarding claim 11, Meierhoefer discloses an ampoule sequence including a plurality of ampoules connected to one another via severable thin wall portions (column 4, lines 45-49 and Fig. 1, separation strip 36).

8. Claims 4-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US Patent 4,502,616) in view of Takanashi et al. (US Patent 4,537,305) in view of Itoh et al. (US Patent 6,042,906), further in view of Komatsu et al. (US Patent 3,892,058).

9. Regarding claim 4, Meierhoefer in view of Takanashi in view of Itoh discloses the invention as substantially claimed, see above. However, Meierhoefer in view of Takanashi in view of Itoh lacks a polyamide layer as claimed [claim 4]. Komatsu discloses a high-temperature sterilizable container comprising a polyamide layer (column 6, lines 23-33 and Fig. 1, inner layer 1). Komatsu solves the problem of providing sterile packaging (column 1, lines 5-10). Komatsu provides the advantage of a heat-sealable material that allows heat sealing during manufacture while allowing heat sterilization (column 7, lines 14-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Meierhoefer in view of Takanashi in view of Itoh with the polyamide of Komatsu in order to provide both heat sealing and heat sterilization capabilities as taught by Komatsu.

10. Regarding claims 5 and 6, Meierhoefer in view of Takanashi in view of Itoh discloses the invention as substantially claimed, see above. However, Meierhoefer in view of Takanashi in view of Itoh is silent with respect to the material used to form ampoule 12, and therefore does not expressly disclose a polyester as claimed [claims 5 and 6]. Komatsu discloses an ampoule comprising a polyester layer (column 6, lines 23-33, and Fig. 1, outer layer 3 comprising polyester). Komatsu provides the advantage of providing a heat resistant layer, which is needed during heat sterilization. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Meierhoefer with the polyester of Komatsu in order to provide a heat sterilizable container. It naturally follows that polyester is a polyol (online encyclopedia, "Polyol").

11. Regarding claim 7, Meierhoefer in view of Takanashi in view of Itoh discloses the invention as substantially claimed, see above. However, Meierhoefer in view of Takanashi lacks a polycycloolefin. Itoh discloses a container comprising a polycycloolefin layer (column 6, lines 40-47 and Fig. 3, intermediate layer 12 comprising cyclic olefin copolymer). Itoh provides the advantage of low moisture permeability (column 1, lines 39-48). Itoh further provides the advantage of retaining flavors, therefore it naturally follows that a polycycloolefin is resistant to movement of volatile substances that may be contained within a medical container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Takanashi as discussed with the

polycycloolefin of Itoh in order to provide low moisture permeability as taught by Itoh, and additionally resist movement of volatile substances.

12. Regarding claim 12, Meierhoefer in view of Takanashi in view of Itoh discloses the invention as substantially claimed, see above. However, Meierhoefer in view of Takanashi in view of Itoh discloses an ampoule having a volume of 0.5 to 20mL (column 4, lines 7-9). Meierhoefer in view of Takanashi in view of Itoh lacks a functional layer as claimed [claim 12]. Komatsu discloses a functional layer having a steam permeation preventing capability and drug absorption/adsorption preventing capability (column 6, lines 23-33 and Fig. 1, layers 1-3). It naturally follows that a foil layer is capable of preventing steam permeation capability and preventing drug absorption/adsorption. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Meierhoefer in view of Takanashi in view of Itoh with the metal foil of Komatsu in order to provide better heat distribution during a sterilization process.

13. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US Patent 6,254,376) in view of Takanashi et al. (US Patent 4,537,305) in view of Itoh et al. (US Patent 6,042,906).

14. Regarding claim 13, Louviere discloses a production method for a drug solution filling plastic ampoule comprising the steps of:

molding a container body by holding a tubular parison between lower split mold pieces (column 5, lines 57-62 and Fig. 1, core pins 68, 70 and slide inserts 26, 28;

column 9, lines 47-65). Louviere discloses forming a hollow plastic article (column 9, lines 31-34) therefore it naturally follows that that Louviere has a step of forming a void in a parison.

A parison is defined as a partially shaped mass of molten glass (online dictionary, "parison"). Applicant has not further defined the term "parison" in the specification, therefore it is given its plain meaning. Liquidized plastic reasonably meets the definition of "parison" in the context of plastic molding.

Louviere discloses a step of filling a drug solution in a container body (column 10, lines 28-37).

Louviere substantially discloses holding a mouth of a container body between upper split mold pieces to form a fusion-bonded portion which seals the mouth of the container body and a holder tab which is connected to the fusion-bonded portion to be used for wrenching off the fusion-bonded portion (column 9, lines 34-41 and Fig. 8, rectangular extension top 240A and nearby neck).

Louviere discloses the invention substantially as claimed. However, Louviere lacks a parison having three or more layers as claimed [claim 13]. Takanashi discloses a medical storage container (column 1, lines 9-14) having:

an innermost layer composed of a polyolefin (column 3, lines 4-14 and Fig. 2, inner layer 3 comprising polyolefin); and

an outmost layer composed of a polyolefin (column 3, lines 4-14 and Fig. 2, outer layer 1 comprising polyolefin). Takanashi provides the advantage of a thermally resistant polymer (column 3, lines 27-31). This advantage is important, since medical

containers are routinely sterilized using high temperatures. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere as discussed with the polyolefin of Takanashi in order to provide thermally resistant polymer during a sterilization process. Takanashi discloses a container including three or more layers (Fig. 1, layers 1-3). Therefore, it naturally follows that Takanashi has a parison having three or more layers. It is the Examiner's position that the polyolefin layers of Takanashi have a drug permeation preventing capability.

Louviere in view of Takanashi discloses the invention as substantially claimed, see above. However, Louviere in view of Takanashi lacks a polycycloolefin as claimed [claim 13]. Itoh discloses an impermeable container (column 1, lines 6-13) having an intermediate layer comprising a polycycloolefin layer (column 6, lines 40-47 and Fig. 3, intermediate layer 12 comprising cyclic olefin copolymer). Itoh provides the advantage of retaining flavors, therefore it naturally follows that a polycycloolefin is resistant to movement of volatile substances that may be contained within a medical container. In other words, the ability to retain flavors as disclosed by Itoh translates into an ability to resist movement of volatile substances. This is a valuable advantage, since medications may comprise volatile substances, which require preservation in order to retain their potency. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere in view of Takanashi as discussed with the polycycloolefin of Itoh in order to provide low moisture permeability as taught by Itoh, and additionally resist movement of volatile substances.

15. Regarding claim 15, Louviere in view of Takanashi in view of Itoh disclose the invention substantially as claimed. However, Louviere lacks an additive as claimed [claim 15]. Takanashi discloses a layer provided as other than an innermost layer and containing an oxygen absorbing agent (column 4, lines 51-55 and Fig. 2, deoxidizer 13). Takanashi provides the advantage of absorbing oxygen, to prevent degradation of a medical solution (column 1, lines 39-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere in view of Takanashi in view of Itoh as discussed with the oxygen absorbing agent of Takanashi in order to prevent degradation of a medical solution as taught by Takanashi.

Takanashi further discloses a layer provided inwards of the layer of the oxygen absorbing agent (cols. 4-5, lines 64-4 and Fig. 1, medical container 12). It is the Examiner's position that container 12 of Takanashi is provided inward of the layer of the oxygen absorbing agent of Takanashi, and substantially prevents drug permeation. Takanashi provides the advantage of storing a medicament such that it can be quickly accessed when needed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Louviere as discussed with the layer provided inwards of an additive-containing layer as taught by Takanashi in order to store medicament.

Response to Amendment

16. Objection to the abstract and IDS applied in the Office Action dated 27 August 2007 is withdrawn in view of the remarks and new abstract filed 28 January 2008.

Response to Arguments

17. Applicant's arguments with respect to claims 1, 3-7, 11-13 and 15 have been considered but are moot in view of the new ground(s) of rejection.

18. Applicant's arguments filed 28 January 2008 have been fully considered but they are not persuasive.

19. Applicant asserts that combining the inventions of Meierhoefer, Komatsu and Itoh do not improve the openability of a container. Examiner notes that this limitation does not appear in the claims.

20. Applicant asserts that Itoh lacks a layer comprising both a polyolefin and a polycycloolefin. Examiner notes that Itoh is relied upon for the limitation of a polycycloolefin, and that Meierhoefer is relied upon for the limitation of a polyolefin.

21. Applicant asserts that Louviere lacks a structure comprising three layers as claimed. Examiner notes that Louviere is relied upon for the limitation of holding a parison, while Takanashi and Itoh are relied upon for the structure of layers as claimed. See the new grounds of rejection above.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761